

NADA Number: 140-890	
Trade Name	Excenel® Sterile Powder Excenel® RTU Excenel Sterile Suspension
Sponsor	Pharmacia & Upjohn Co.
Ingredients	Ceftiofur Hydrochloride
Species	Cattle, excluding veal calves Swine, no use class stated or implied
Routes of Administration	Intramuscular Subcutaneous (cattle)
Dose Form	Liquid (suspension)
Drug Form	Liquid (suspension)
Dispensing Status	RX
Patent Number	4902683 5736151
Exclusivity	Granted for use in cattle for acute metritis associated with bacterial organisms susceptible to ceftiofur. Granted for use in a new species (cattle). Granted for the treatment and control of swine bacterial respiratory disease
Dosage Amount, Indications & Limitations	<p>522.313b Ceftiofur hydrochloride.</p> <p>Specifications: Each milliliter of ceftiofur hydrochloride suspension contains 50 milligrams (mg) of ceftiofur equivalents.</p> <p>Conditions of use:</p> <p>Swine</p> <p>Amount: 3 to 5 milligrams per kilogram of body weight by intramuscular injection. Treatment should be repeated at 24-hour intervals for a total of 3 consecutive days.</p> <p>Indications: For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with <i>Actinobacillus pleuropneumoniae</i>, <i>Pasteurella multocida</i>, <i>Salmonella choleraesuis</i>, and <i>Streptococcus suis</i>.</p> <p>Limitations: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Treated swine must not be slaughtered for 4 days following the last treatment.</p> <p>Cattle (excluding veal calves)</p> <p>Amount: 1.1 to 2.2 mg/kg of body weight by intramuscular or subcutaneous injection, at 24-hour intervals for 3 to 5 consecutive days. For bovine</p>

	<p>respiratory disease, 2.2 mg/kg of body weight may be administered twice at a 48-hour interval. For acute metritis, administer 2.2 mg/kg of body weight daily for 5 consecutive days.</p> <p>Indications: For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with <i>Mannheimia haemolytica</i>, <i>P. multocida</i>, and <i>Histophilus somni</i>; acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with <i>Fusobacterium necrophorum</i> and <i>Bacteroides melaninogenicus</i>; and acute metritis (0 to 14 days post-partum) associated with bacteria susceptible to ceftiofur.</p> <p>Limitations: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Treated cattle must not be slaughtered for 3 days following the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p>
Tolerances	<p>A tolerance for residues of ceftiofur in edible tissue of poultry and sheep is not required.</p> <p>Tolerances in swine for desfuroylceftiofur (marker residue) in edible swine tissues are 0.25 part per million in kidney (target tissue), 3 parts per million in liver, and 2 parts per million in muscle.</p> <p>Tolerances are established for residues of desfuroylceftiofur (marker residue) in edible cattle tissues at 0.4 parts per million in kidney (target tissue), 2 parts per million in the liver, 1 part per million in muscle, 100 parts per billion in milk.</p>